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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,243	11/12/2003	Solomon S. Steiner	PTD 103 CON (3)	6406
23579	7590	04/06/2006	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 04/06/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/706,243	STEINER ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 16-36 are pending in this application.

#### ***Action Summary***

1. Examiner acknowledges the correction of the grammatical error in claim 35.
2. The rejection of claims 23-26 over claims 1-12 of US 6,428,771 and claims 23, 26-28, 31-33 and 36 over claims 1, 2, 4-7 and 10-12 of US 6,071,497 over the judicially created doctrine of obviousness-type double patenting is hereby withdrawn as applicant has filed a terminal disclaimer.
3. The rejection of claims 16 and 18 under 35 U.S.C. 103(a) over Domb is hereby withdrawn with respects to applicants arguments.
4. The rejection of claims 16 and 17 under 35 U.S.C. 103(a) over Boyes et al. is being maintained for the reasons stated in the previous office action.
5. The rejection of claims 16, 19 and 20 under 35 U.S.C. 103(a) over Debenedetti et al. is being maintained for the reasons stated in the previous office action.
6. The rejection of claims 16 and 21 under 35 U.S.C. 103(a) over Sugaya et al. is being maintained for the reasons stated in the previous office action.
7. The rejection of claim 22 under 35 U.S.C. 103(a) over Boyes et al. in view of Hunt et al. is being maintained for the reasons stated in the previous office action.

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***Response to Arguments***

8. Applicant's arguments filed December 27, 2005 have been fully considered but they are not persuasive.

Applicants argue that the prior art references of Boyes et al., Debenedetti et al., Sugaya et al. and Boyes et al. in view of Hunt et al. does not disclose the release of the active agent from the microcapsule are pH-dependent. It is furthered argued that Debenedetti et al. and Sugaya et al. does not teach the particles being delivered by inhalation. It is understood by the examiner that the microparticles are formed from a material that releases the drug at a pH of greater than 6.0. Since the cited references teach microparticles formed from the same material as claimed by applicant, then the limitation of releasing the drug at a pH of greater than 6.0 would be met. With respect to the method of delivery (inhalation v. injection), With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. In re Madder et al. 143 USPQ 248.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 16-18 and 22 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for a material which releases a drug at a pH of greater than 6, which includes mixed amino acids, lipids or surface-active agents. The disclosure of mixed amino acids in the specification indicate that the mixed amino acids must be in the form of a polymer (pg. 2, lines 5-7).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 23-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: that the air must be compressed or pressurized (spec. page 23). Also in claims 23-26 the release pH is an essential element (Spec. pgs. 17 & 18).

11. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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***Conclusion***

12. Claims 16-36 are rejected.


***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1000